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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,220	03/22/2004	Kazunari Yamaguchi	Q80490	9623
23373	7590	09/22/2008	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	
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			09/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/805,220

Applicant(s)

YAMAGUCHI ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 20-22, 24 and 26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 17, 20-22, 24 and 26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response and amendment filed on July 3, 2008 has been entered. Claims 17, 20-22, 24 and 26 are pending and under examination. Claim 25 has been cancelled, rendering any rejection(s) over claim 25 moot.

Claims Summary

2. The claims are drawn to a method for determining whether a subject has been infected with Borna Disease Virus (BDV) by detecting IgM and/or IgG antibodies to BDV antigen polypeptides. The method comprises:

(a) providing a support sensitized with a p10 BDV synthetic antigen polypeptide, and a p24 or p40 BDV antigen polypeptide; or, a support sensitized with p10, p24 and p40;

(b) reacting the support with a sample that is suspected of containing anti-BDV antibodies;

(c) detecting both IgM and IgG antibody, thus detecting infection.

Specifically, the polypeptide from the p24 region is SEQ ID NO: 1. The polypeptide from the p40 region is SEQ ID NO: 3. The polypeptide from the p10 region is SEQ ID NO: 8.

Note that the claims are under examination with regard to SEQ ID NO: 1, 3 and 8 as a result of restriction/species election. SEQ ID NO: 5 and 7 are not under examination and are not eligible for rejoinder. SEQ ID NO: 6 and 8 are species of each other, however, SEQ ID NO: 8 has been elected.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 20-22, 24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi *et al.* (*Ann. Clin. Biochem.* 2001, 38:348-355, "Yamaguchi"), in view of Watanabe *et al.* (*J. Vet. Med. Sci.*, 2000, 62(7):775-778, "Watanabe"), as evidenced by Planz *et al.* (*Journal of Virology*, 1999, 73:6251-6256, "Planz") and further in view of Hatalski *et al.* (*Journal of Virology*, February 1995, 69(2):741-747, "Hatalski"), and Carbone, K.M. (*Clin. Micro. Rev.*, 2001, 14(3):513-527, "Carbone"). Although the claims have been amended to incorporate the limitations of cancelled claim 25 into all the claims, the rejection of record remains the same because the embodiment of claim 25 was rejected.

Response to Arguments

4. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:
- Applicant argues that Watanabe does not provide motivation to modify Yamaguchi's method to measure antibodies to p10. Applicant argues that one would have only been motivated to detect p40 and p24, not IgM and IgG antibodies that bind to p10, as instantly claimed. Applicant asserts that neither Watanabe nor Yamaguchi suggest

the desirability of modifying Yamaguchi's method to detect p10 antibodies.

Applicant asserts that improper hindsight is the basis for the obviousness rejection.

- As previously set forth by the Office, it would have been obvious to include the detection of p10 in Yamaguchi's method. One would have motivated to detect anti-p10 antibodies, as well as anti-p40 and anti-p24 antibodies for the purpose of increasing the sensitivity of Yamaguchi's method. Watanabe suggests that antibodies to individual viral proteins and BDV-specific antigens are useful for establishing diagnostic methods (page 777, second column, last paragraph). The Office acknowledges that neither Yamaguchi nor Watanabe actually state that the detection p10 would be useful in Yamaguchi's method, however, the motivation comes from the improved diagnostic method that would result from increasing the sensitivity of Yamaguchi's method by detection anti-p10 antibodies in addition to anti-p24 and anti-p4 antibodies.
- In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

- Applicant argues Hatalski does not cure the deficiencies of Yamaguchi or Watanabe. Applicant asserts that Hatalski was published before Yamaguchi and Watanabe, yet provides no additional guidance to encourage or motivate one to modify the ECLIA method of Yamaguchi to test for IgM and IgG. Applicant argues that the teachings of Hatalski related to the role of neutralizing antibodies and determining their effect on the pathogenesis of BDV.
- The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The Office acknowledges that the teachings of Hatalski relate to subject matter outside the scope of the instant invention, however, Hatalski's method of testing for the presence of both IgG and IgM antibodies to recombinant and native BDV proteins using the method of electrochemiluminescence is instructive for one of ordinary skill in the art. One would have been motivated to modify Yamaguchi's method by testing for the presence of IgM as well as IgG in order to detect evidence of an infection as early as possible.
- Applicant argues that Carbone is a general review article, but adds nothing further to the teachings of Yamaguchi, Watanabe and Hatalski because it simply teaches that IgM is first raised upon viral infection, a fact already recognized in the art at the time

of the invention. Applicant argues that although IgM was known, it would not have been predictable for one to include IgM for the purpose of diagnosing BDV infection because it disappears rapidly.

- In response to Applicant's arguments, the sensitivity of Yamaguchi's method would be increased by including a test for IgM because it appears first after infection. The detection of IgM would at least indicate that infection has taken place at some point, and allows the detection of an infection with BDV in the absence of IgG. Note that the presence of IgG is also detected, thus accounting for the possible absence of IgM (depending on when the sample is taken relative to infection). The Office acknowledges that a diagnosis of active or cleared infection with BDV cannot be determined with the detection of IgG or IgM, but the detection of the antibodies will indicate that the subject has been infected. (Note that the claims do not recite the detection of an active or past infection.

Even if the claims recited such a limitation, they would not be enabled.)

- Applicant points to the statement in Carbone which basically says that the presence of antibodies to BDV does not necessarily lead to a conclusion of whether the infection is present or cleared. Applicant argues that given this teaching, one would have only been motivated to test for IgG. Applicant argues that Carbone appears to discourage or teach away from a single test for BDV IgG, rather, suggesting a series of tests for BDV infection.
- In response to Applicant's argument, it is acknowledged by the Office that the detection of antibodies alone will not determine an active or past infection, only

that an infection has occurred. Carbone's statement relates to the determination of an active or past infection. The claims are not drawn to the detection of an active or past infection, nor are the claims limited to the steps of detecting IgM and IgG. Given that Hatalski demonstrates that IgM is present in response to BDV infection, and Carbone indicates that IgM is often the first serological evidence of BDV infection, one would have had a reasonable expectation of success that testing for the presence of IgM and IgG would have worked in Yamaguchi's method to increase sensitivity and detect evidence of an infection as early as possible. Therefore, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

6. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, TC1600